

Appln. No. 10/789,054

Response dated August 24, 2006

Response to Restriction Requirement dated September 22, 2006

REMARKS

In the Office Action dated August 24, 2006, the Examiner issued a requirement for restriction under 35 U.S.C. §121 categorizing original Claims 1-64 as follows:

I. Claims 1-56 and 61-64, drawn to a pharmaceutical formulation comprising a muscle relaxant and a COX II inhibitor, classified in class 514, subclass 379.

II. Claims 57-60, drawn to a method for the treatment or prevention of pain and/or spasticity comprising administering a pharmaceutically effective amount of the pharmaceutical formulation of Group I, classified in class 514, subclass 379.

Applicants elect, with traverse, the subject matter of the claims of Group I, i.e., Claims 1-56 and 61-64, for examination in this application. Applicants further elect the following species: (1) hydroxypropyl methylcellulose as the water soluble celluloses (Claims 19-21); (2) mannitol as the hydrophilic pore former (Claims 22-24); (3) a cellulose ether as the matrix layer (Claims 27-35); (4) stearic acid as the excipient (Claims 36-45 and 47-54) and (5) valdecoxib as the COX II inhibitor.

Applicants respectfully request that the Examiner withdraw, or at the very least modify, the requirement for restriction and provide an action on the merits of the nonelected claims.

It is respectfully submitted that the requirement for restriction between at least the claims of Group I and Group II is improper and should be withdrawn.

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Restriction is proper only if the claims are either independent or patentably distinct and the search and examination of the entire application would impose a serious burden on the examiner (MPEP § 803). Applicant respectfully traverses the restriction requirement because the Examiner has not provided sufficient reasons to show that such a burden exists. Here, all of applicant's claims are directed either to a pharmaceutical formulation (Claims 1-56 and 61-64); or to a method for the treatment or prevention of pain and/or spasticity comprising administering a pharmaceutically effective amount of the pharmaceutical formulation of Group I (Claims 57-60) and as the Examiner has noted, each of Groups I and II are classified within Class 514, subclass 379. Applicants therefore submit that the Examiner, in searching for the subject matter of the claims in Class 514, subclass 379, would necessarily find art related to the pharmaceutical composition of the claims of Group I; as well as the method for the treatment or prevention of pain and/or spasticity by administering the pharmaceutical composition of the claims of Group II.

Accordingly, applicants respectfully request that the Examiner withdraw, or at the very least modify, the requirement for restriction and provide an action on the merits of nonelected Claims 57-60.

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For the foregoing reasons, applicant respectfully submits that all of the claims of the application as presented herein, including the nonelected claims, are in condition for examination on the merits. Early favorable action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Michael E. Carmen". The signature is fluid and cursive, with the first name "Michael" being the most prominent.

Michael E. Carmen

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